Summer 8-16-2016

Keeping an Eye on the FDA

Rodney Richmond
Harding University College of Pharmacy, rrichmond@harding.edu

New Drugs

By Rodney G. Richmond, RPh, MS, CGP, FASCP

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This column, presented by the Harding University College of Pharmacy, aims to briefly highlight information on new molecular or biological entities, new indications, or significant new dosage forms recently approved by the FDA.

The pace picked-up in the 2nd quarter with approval of 13 new molecular/biological entities, one new device, and several new dosage forms. In the ebb-and-flow of things the FDA also announced withdrawal from the market two niacin/statin combination products (Advicor® and Simcor®) used to treat hypercholesterolemia, citing reasons of safety and effectiveness. The antidepressant Brintellix was changed to Trintellix to decrease the risk of name confusion with Brilinta®.

Chronic Care: Nuplazid™ (pimavanserin) was granted breakthrough therapy designation and priority review for the treatment of Parkinson's disease-related hallucinations and delusions. Cerêve™ Sleep System became the first and only device cleared to treat insomnia through reduced latency to stage 1 and 2 sleep by gently cooling the forehead. Opioids remained in the headlines with the FDA unveiling new class-wide safety labeling changes for immediate-release opioids, and amid controversy the CDC releasing their Guideline for Prescribing Opioids for Chronic Pain. Three new opioid formulations were approved including Xtampza™ER (oxycodone, extended-release capsule) and Vantrela ER (hydrocodone, extended-release tablet) for chronic pain, and Probuphine® (buprenorphine), a 6-month implant for maintenance of opioid dependence.

Hematology/Oncology: Two diagnostic imaging agents were approved for use with PET scan imaging. Axumin (fluciclovine F 18) was approved to help detect recurrent prostate cancer, and through priority review Netspot was designated as an orphan drug as the first kit for the preparation of gallium Ga 68 dotatate for detecting rare neuroendocrine tumors. Tecentriq™ (atezolizumab) received accelerated priority review approval with breakthrough therapy designation as the first-in-class PD-L1 inhibitor for treating urothelial carcinoma. Venclexta™ (venetoclax) also received accelerated priority review approval with breakthrough therapy designation as an orphan drug targeted to treat chronic lymphocytic leukemia. Although not an oncologic agent, Defitelio® (defibrotide) was given priority review as an orphan drug to treat the rare but frequently fatal hepatic veno-occlusive disease in patients undergoing hematopoietic stem cell transplantation.

Specialty Products: An eclectic array of niche drugs have been recently approved. Anthim® (obiltoxaximab), approved under the FDA's "animal efficacy rule" which is reserved for approval of biological products when human efficacy studies are not ethical or feasible, is for the prophylaxis and treatment of inhalational anthrax. Vaxchora™ (cholera vaccine) received a tropical disease priority review voucher as the first vaccine in the U.S. for the prevention of cholera. Cinqair® (reslizumab) was approved as an anti-eosinophil maintenance drug for severe asthma in adults. Zinbryta™ (daclizumab), available only through a limited-distribution REMS program, was approved for relapsing forms of multiple sclerosis. Taltz® (ixekizumab) is for moderate-to-severe plaque psoriasis and requires patients to receive a Medication Guide. Kovaltry® (Factor VIII, recombinant) received a nod to treat hemophilia A, the most common type of hemophilia. Ocaliva™ (obeticholic acid) was granted an accelerated review as an orphan drug to treat primary biliary cholangitis.

New Dosage Forms: Significant new dosage forms that were approved this quarter include: Bevespi Aerosphere™ (glycopyrrolate/formoterol, inhalation aerosol) for COPD; Descovy® (emtricitabine/tenofovir/alafenamide, tablet) for HIV-1 infection; Cabometyx™ (cabozantinib, tablet) for advanced renal cell carcinoma; Inflectra™ (infliximab-dyyb, injection) as a biosimilar to Remicade; Jentadueto®XR (linagliptin/metformin, extended-release tablet) for type 2 diabetes; Otovel (ciprofloxacin/fluocinolone, otic solution) for acute otitis media with tympanostomy tubes; Photrexa® (riboflavin 5'-phosphate, ophthalmic solution) for progressive keratoconus. §

DRUG	INDICATION	ROUTE	DOSING	ESTIMATED COST	
SPECIALTY PRODUCTS					
Anthim® (obiltoxaximab)	Inhalational anthrax, prophylaxis and treatment	IV	Single-Dose	-	-
Cinqair® (reslizumab)	Severe asthma, maintenance treatment	IV	Once-Monthly	$2,000	per Month
Kovaltry® (Factor VIII, recombinant)	Treatment of hemophilia A	IV	Variable	$4,000	per Dose
Ocaliva™ (obeticholic acid)	Primary biliary cholangitis	PO	Once-Daily	$6,840	per Month
Taltz® (ixekizumab)	Plaque psoriasis, moderate-to-severe	SubQ	Titrated Course	$4,924	per Injection
Vaxchora™ (cholera vaccine)	Prevention of cholera	PO	Single-Dose	-	-
Zinbryta™ (daclizumab)	Relapsing forms of multiple sclerosis	SubQ	Once-Monthly	-	-
ONCOLOGY PRODUCTS					
Axumin (Fluciclovine F 18)	Imaging agent, suspected prostate cancer recurrence	IV	Single-Use	-	-
Defitello® (defibrotide)	Hepatic veno-occlusive disease, post-stem cell transplant	IV	Q6 Hours x3-8 weeks	$166,320	per Course
Netspot (gallium Ga 68)	Imaging agent, rare neuroendocrine tumors	IV	Single-Use	-	-
Tecentriq™ (atezolizumab)	Urothelial carcinoma	IV	Q3 Weeks	$10,344	per Month
Venclexta™ (venetoclax)	Chronic lymphocytic leukemia	PO	Once-Daily	$11,472	per Month
CHRONIC CARE					
Nuplazid™ (pimavanserin)	Parkinson's disease psychosis	PO	Once-Daily	$2,340	per Month

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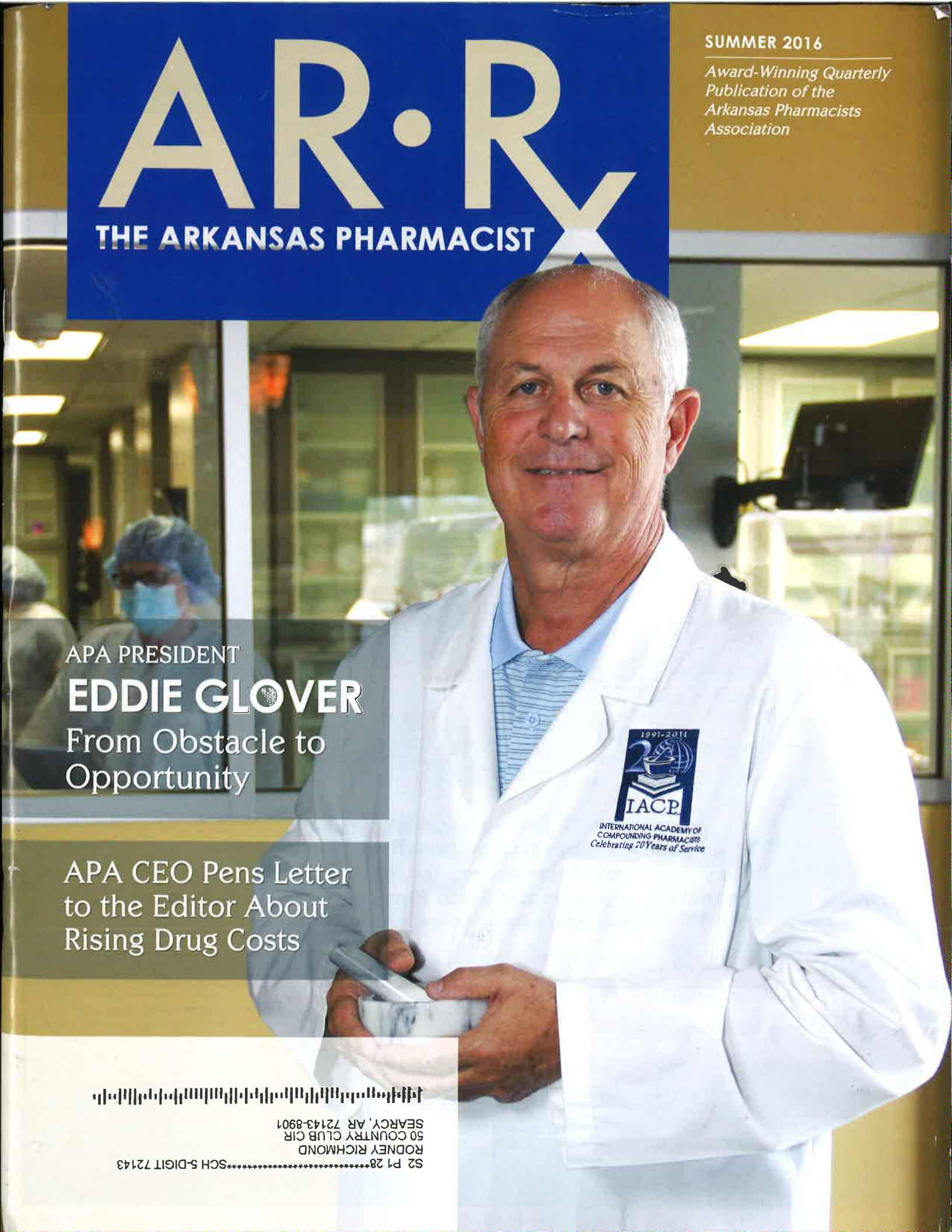
THE ARKANSAS PHARMACIST

SUMMER 2016

Award-Winning Quarterly Publication of the Arkansas Pharmacists Association



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